fusion. *Timblin v. Kent Gen. Hosp., Del. Supr., 640 A.2d 1021 (1990).* The determination of unfair prejudice is a matter within the bounds of discretion of the trial court. *Mercedes-Benz of N. Am., Inc. v. Norman Gershman's Things to Wear, Inc., Del. Supr., 596 A.2d 1358 (1991).* To justify exclusion under Rule 403 at the pretrial stage, the court must have before it "a record complete enough on the point at issue to be considered a virtual surrogate for a trial record." *In re Paoli Railroad Yard PCB Litigation, 916 F.2d 829, 859-60 (3d Cir. 1990).*

Defendants in this case allege that "[a] very real danger exists that the jury will rule against Certain Defendants based solely on the experts' unfounded speculations about why insurance companies defend coverage actions." Clearly, Defendants' description of the expert testimony as "unfounded speculations" cannot serve as a "virtual surrogate" for the witnesses' actual testimony, and therefore exclusion under Rule 403 is premature. *In re Paoli Railroad, 916 F.2d at 860.* Furthermore, the Court finds that the alleged danger does not substantially outweigh the probative value of enabling [*14] the jury to evaluate Defendants' conduct against industry standards. *Marx & Co. v. Diners' Club, Inc., 550 F.2d at 509.* Having found that the experts' testimony will assist the both the Court and the jury in understanding the evidence, the court need not address Defendants' argument that the testimony will mislead and confuse the jury.

C. Conclusion

For all the foregoing reasons, the Defendants' motion in limine to bar the expert testimony of Richard Stewart and Michael Jackson is hereby **DENIED**.

IT IS SO ORDERED.

II. MOTION TO BIFURCATE TESTIMONY OF RICHARD STEWART

NAPC has moved to bifurcate the testimony of its expert Richard Stewart into the following segments: first, an overview of the insurance market with respect to comprehensive general liability policies sold to major corporations; second, information as to customs and practices in the insurance market specifically in relation to conduct and activities at the Fresno site. n3

> n3 In its brief, NAPC states that "Mr. Stewart will provide expert testimony as to how the insurance policies sold to NAPC should be interpreted to provide insurance coverage to NAPC for the claims at issue in the trial." Such testimony from an expert witness is legal opinion testimony and as such is inadmissible. See discussion of expert witnesses offering legal conclusions. supra, at 7-9.

[*15]

Defendants contend that NAPC's assertions as to saving time and avoiding jury confusion provide insufficient rationale for bifurcating Stewart's testimony. The Court disagrees. [HN11] In a case which involves a complex industry and highly specialized evidence, and which also promises to last for several months, the efficient presentation of evidence is a critical tactical issue for both sides. Unless there is danger of prejudice to the opposition, counsel controls the presentation of its case. When a dispute arises, this Court is to

> exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to (1) make the interrogation and presentation effective for the ascertainment of the truth, (2) avoid needless consumption of time, and (3) protect witnesses from harassment or undue embarrassment.

D.R.E. 611(a). Further, "[HN12] abuse of discretion is likely to arise only if opportunity is completely denied to present evidence, impeach witnesses, support the credibility of impeached witnesses, or refute new points raised by the opponent." Handbook of Federal Evidence, § 611.4, at 523-24 (West 3d ed.). The Court concludes that there is [*16] no prejudice to the Defendants since they have prior notice of the bifurcation and will have ample opportunity to cross examine Stewart as to all of his testimony. The Court is also satisfied that the two segments of Stewart's testimony will in fact enhance the presentation of the evidence and the jury's ability to apply the law to facts of the case.

On the issue of whether counsel may consult with Stewart between the two segments of his testimony, the Court finds that this situation is analogous to a hiatus in the taking of a deposition. In amending [HN13] Super.Ct.Civ.R. 30(d)(1), the Delaware Supreme Court implicitly acknowledged that attorney/witness consultations during an interim of five days or more is presumptively proper and will not cause prejudice to the opposition. Since the hiatus between the portions of Stewart's testimony may be as long as four weeks and Stewart will not be sequestered, the Court finds that consultation between counsel and Stewart will not prejudice the Defendants. Defendants have ample notice of the bifurcation and will have the opportunity to cross-examine the witness at trial.

For all the foregoing reasons, NAPC's motion in limine to bifurcate the [*17] testimony of Richard Stewart is hereby GRANTED.

IT IS SO ORDERED.

Judge Vincent A. Bifferato

LEXSEE 2004 US DIST LEXIS 18638

PHARMASTEM THERAPEUTICS, INC., Plaintiff, v. VIACELL INC., et al., Defendants.

C.A. No. 02-148 GMS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2004 U.S. Dist. LEXIS 18638

September 15, 2004, Decided

SUBSEQUENT HISTORY: [*1] Reconsideration granted by, in part, Injunction denied by, Judgment entered by *Pharmastem Therapeutics v. Viacell, Inc., 2004 U.S. Dist. LEXIS 25176 (D. Del., Dec. 14, 2004)*

PRIOR HISTORY: *PharmaStem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 17137 (D. Del., Sept. 30, 2003)*

DISPOSITION: ViaCell, Cyro-Cell, CorCell, and CBR Systems' motion for judgment as a matter of law or for new trial granted in part. PharmaStem, Inc.'s motion for enhanced damages, attorneys' fees, pre-judgment interest and post judgment interest denied. PharmaStem, Inc.'s motion to strike and for a permanent injunction denied.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent owner filed suit against defendants for infringement of two patents directed toward: (1) cryopreserved therapeutic compositions containing hematopoietic stem cells, and (2) methods pertaining to the therapeutic use of such compositions. After a jury returned a verdict for the owner, defendants filed a renewed motion for judgment as a matter of law or, in the alternative, a motion for a new trial or a remittitur.

OVERVIEW: In the owner's infringement suit, defendants asserted the defenses of invalidity for anticipation, inequitable conduct, and obviousness. A jury found that the patents were valid and that defendants willfully infringed their claims. On defendants' motion, the court held that defendants were entitled to judgment as a matter of law on the claim of infringement with respect to the second patent because, although there was substantial evidence to support the jury's verdict that the patent was not obvious, anticipated, or indefinite, the owner failed to adduce evidence that defendants sold or offered to sell a component of the patented process, specifically, cord blood units. Thus, the owner failed to prove that defendants contributorily infringed the second patent. The court further held that defendants were entitled to a new trial on the issue of infringement with respect to the first patent because the testimony of the owner's infringement expert--that 100 percent of defendants' cord blood units infringed the first patent--was based upon a legally improper methodology and was unreliable as a matter of law under Daubert. Thus, it should not have been admitted.

OUTCOME: The court entered judgment as a matter of law that defendants did not infringe the second patent and granted a partial new trial on the issue of infringement of the first patent.

CORE TERMS: blood, patent, cord, cell, stem, infringement, transplant, invention, new trial, hematopoietic, matter of law, infringe, adult, inventor, transplantation, composition, inequitable conduct, reconstitution, cryopreserved, substantial evidence, subject matter, indefiniteness, anticipation, therapeutic, invalid, skill, great weight, reexamination, obviousness, progenitor

LexisNexis(R) Headnotes

Civil Procedure > Trials > Judgment as Matter of Law
[HN1] Pursuant to *Fed. R. Civ. P. 50*, a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial if there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.

Civil Procedure > Trials > Judgment as Matter of Law
[HN2] If a court denies a motion for judgment as a matter of law during trial, the motion may be renewed within 10 days of entry of judgment in the case. *Fed. R. Civ. P. 50(b)*.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence
Civil Procedure > Trials > Judgment as Matter of Law
[HN3] To prevail on a renewed motion for judgment as a matter of law following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they are, that the legal conclusions implied by the jury's verdict cannot in law be supported by those findings.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence
[HN4] Substantial evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence
[HN5] In assessing the sufficiency of the evidence supporting a jury's findings, a court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence
[HN6] In assessing the sufficiency of the evidence supporting a jury's findings, the appropriate inquiry is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence
[HN7] In assessing the sufficiency of the evidence supporting a jury's findings, a court may not determine the credibility of the witnesses nor substitute its choice for that of the jury between conflicting elements of the evidence.

Civil Procedure > Relief From Judgment > Motions for New Trial
[HN8] A court may grant a new trial pursuant to *Fed. R. Civ. P. 59* for any of the reasons for which new trials have been granted in actions of law in the courts of the United States. *Fed. R. Civ. P. 59(a)*.

Civil Procedure > Relief From Judgment > Motions for New Trial
[HN9] A court should grant a new trial in a jury case only if the verdict is against the weight of the evidence and a miscarriage of justice will result if the verdict is to stand. In making this determination, the trial judge should consider the overall setting of the trial, the character of the evidence, and the complexity or simplicity of the legal principles which the jury had to apply to the facts.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Civil Procedure > Jury Trials > Province of Court & Jury
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN10] Whether or not a patent is obvious over the prior art is a question of law.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Nonobviousness > Elements & Tests > Claimed Invention as a Whole
[HN11] See *35 U.S.C.S. § 103*.

Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN12] An invention is invalid if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent.

Patent Law > Nonobviousness > Elements & Tests > Hindsight
[HN13] Obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the invention.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN14] The United States Supreme Court has set forth four factors relevant to determining obviousness: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) other secondary considerations.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN15] Both a suggestion to make a composition or carry out a claimed process and a reasonable expectation of success must be found in the prior art to support a conclusion that a patent is obvious.

Patent Law > Anticipation & Novelty > Description in Publications
[HN16] An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art

and that such existence would be recognized by persons of ordinary skill in the field of the invention.

Patent Law > Claims & Specifications > Definiteness > General Overview
[HN17] See *35 U.S.C.S. § 112*.

Patent Law > Claims & Specifications > Definiteness > General Overview
[HN18] *35 U.S.C.S. § 112* requires a patentee to provide the public with clear notice of what activities infringe the patent. If the claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.

Patent Law > Claims & Specifications > Claim Language > General Overview
Patent Law > Claims & Specifications > Definiteness > Precision Standards
Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN19] If patent claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.

Civil Procedure > Jury Trials > Province of Court & Jury
Patent Law > Claims & Specifications > Definiteness > General Overview
[HN20] Indefiniteness is a question of law for the court.

Civil Procedure > Jury Trials > Province of Court & Jury
Patent Law > Claims & Specifications > Definiteness > General Overview
[HN21] In a jury trial, if there are disputed factual issues related to indefiniteness, they may be submitted to the jury for resolution.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Claims & Specifications > Definiteness > General Overview
[HN22] As a patent is presumed valid, a party asserting a defense of invalidity on the basis of claim indefiniteness bears the burden of proof by clear and convincing evidence.

Patent Law > Subject Matter > Products > Manufactures
Patent Law > Infringement Actions > Infringing Acts > General Overview
Patent Law > Subject Matter > Products > Machines
[HN23] See *35 U.S.C.S. § 271*(c).

Patent Law > Infringement Actions > Infringing Acts > Sale
Patent Law > Infringement Actions > Infringing Acts > Contributory, Indirect & Induced Infringement
[HN24] Liability under *35 U.S.C.S. § 271*(c) is clearly dependant upon the accused infringer's selling or offering to sell a component of a patented process.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
[HN25] Every patent receives the presumption that its inventors are the true and only inventors. Invalidity for failure to name an inventor must be established by clear and convincing evidence. To be a joint inventor, one must contribute in some significant manner to the conception of the invention. Specifically, each person claiming to be an inventor must have contributed to the conception of the invention. Beyond conception, the purported inventor must demonstrate that he made a contribution to the claimed invention that is not insignificant in quality, when contribution is measured against the dimension of the full invention, and did more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Effect of Inequitable Conduct
[HN26] The burden is on a party seeking to invalidate a patent to prove inequitable conduct by clear and convincing evidence.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements
[HN27] One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the Patent & Trademark Office. Materiality and intent to deceive are distinct factual inquiries, and each must be shown by clear and convincing evidence.

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Duties

[HN28] Patent applicants have a duty to disclose to the Patent & Trademark Office any material prior art or other information cited or brought to their attention in any related foreign application.

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Duties
[HN29] A finding of inequitable conduct for nondisclosure of information requires proof that the applicant made a deliberate decision to withhold a known material reference from the Patent & Trademark Office.

Evidence > Witnesses > Expert Testimony
[HN30] *Fed. R. Evid. 702* has three requirements as to expert opinions: (1) the witness must be an expert; (2) the witness must testify to scientific, technical, or other specialized knowledge; and (3) the testimony must assist the trier of fact. The us1 Supreme Court's decision in Daubert, established a gatekeeping role for trial court judges in determining the admissibility of expert testimony on scientific evidence. When an expert bases opinion testimony on scientific knowledge, the testimony will not be admitted unless it is derived by the scientific method and is supported by "appropriate validation." This standard of evidentiary reliability focuses on the scientific validity of the expert's methods rather than the soundness of his specific conclusions. The inquiry into the reliability of, scientific evidence requires a determination as to its scientific validity. An expert's opinion is reliable if it is based on the "methods and procedures of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his or her belief.

Evidence > Relevance > Confusion, Prejudice & Waste of Time
Evidence > Witnesses > Expert Testimony
[HN31] An *Fed. R. Evid. 403* exclusion of expert testimony is proper where the evidence is susceptible of elucidation without specialized knowledge and jury can ascertain it through common sense.

COUNSEL: Philip A. Rovner, Esquire of Potter Anderson & Corroon LLP, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Paul J. Andre, Esquire, Lisa Kobialka, Esquire of Perkins Coie LLP, Menlo Park, California.

Jeffrey L. Moyer, Esquire of Richards Layton & Finger, Wilmington, Delaware, Richard D. Kirk, Esquire of Morris James Hitchens & Williams LLP, Wilmington, Delaware, and Robert F. Stewart, Esquire of Dilworth Paxson LLP, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Paul F. Ware, Esquire, John C. Englander, Esquire, James C. Rehnquist, Esquire, [*2] James W. McGarry, Esquire, and Elaine Herrmann Blais, Esquire of Goodwin Procter LLP, Boston, Massachusetts; William F. Abrams, Esquire, Thomas F. Chaffin, Esquire and Randal Ivor-Smith, Esquire of Pillsbury Winthrop LLP, Palo Alto, California; and James L. Rodgers, Esquire, Evelyn H. McConathy, Esquire, and Lisa Burgin Conte, Esquire of Dilworth Paxson LLP, Philadelphia, Pennsylvania.

JUDGES: Gregory M. Sleet, UNITED STATES DISTRICT JUDGE.

OPINIONBY: Gregory M. Sleet

OPINION:

MEMORANDUM OPINION

September 15, 2004

Wilmington, DE

SLEET, District Judge

I. INTRODUCTION

On February 22, 2002, PharmaStem Therapeutics, Inc. ("PharmaStem") filed suit against ViaCell, Inc. ("ViaCell"), Cryo-Cell International, Inc. ("Cryo-Cell"), CorCell, Inc. ("CorCell"), StemCyte, Inc. ("StemCyte"), CBR Systems, Inc. ("CBR"), Birthcells Technology, Inc. ("Birthcells"), Nustem Technologies, Inc. ("Nustem"), and Bio-Cell, Inc. ("Bio-Cell") (collectively "ViaCell" or "the defendants") n1 , alleging infringement of *United States Patents Nos. B1 5,004,681* (" [*3] *'681 Patent*") and *5,192,553* (" *'553 Patent*") (collectively "the Patents-In-Suit"). The Patents-In-Suit are generally directed toward cryopreserved therapeutic compositions containing hematopoietic stem cells obtained from umbilical cord or placental blood of a newborn, the '681 Patent, and methods pertaining to the therapeutic use of such compositions, the '553 Patent.

n1 A default judgment was subsequently rendered against NuStem on July 10, 2002. StemCyte and PharmaStem entered a settlement agreement before trial, and StemCyte accordingly was dismissed from this action on October 21, 2003.

ViaCell asserted the defenses of invalidity for anticipation, indefiniteness, inequitable conduct and obviousness. The court held a *Markman* hearing and issued an order construing the disputed terms of the *'681* and

'553 Patents on January 13, 2003. A jury trial commenced on October 10, 2003. During trial, both parties properly moved for judgment as a matter of law ("JMOL") pursuant to *Rule 50(a) of the Federal Rules of Civil Procedure.* [*4] The court reserved ruling on all JMOL motions.

On October 29, 2003, the jury returned a unanimous verdict on all claims in favor of PharmaStem. The jury found that each of the defendants infringed the claims of the *'681* and '553 Patents, and that each of the defendant's infringement of those patents was willful. The jury also upheld the validity and enforceability of the Patents-In-Suit, found that PharmaStem did not commit any antitrust violation, and awarded PharmaStem past damages in the amount of $ 7,126,544.92. The court entered judgment on the verdict on October 30, 2003.

Following the jury's verdict, ViaCell filed a renewed motion for judgment as a matter of law, and, in the alternative, a motion for a new trial or for a remittitur. Defendants CBR, CorCell, and Cryo-Cell joined in Viacell's motions and submitted individual memoranda addressing issues specific to each of them. ViaCell filed another alternative motion, in which the three other defendants also joined, for findings by the court and/or to alter or amend judgment pursuant to *Federal Rule of Civil Procedure 52, 59(e)* and/or the court's equitable power. PharmaStem filed a motion for enhanced damages, attorneys' [*5] fees, pre judgment interest and post judgment interest, a motion for a permanent injunction, as well as a motion to strike the affidavit of Chris Adams submitted in support of ViaCell's motion to alter or amend the judgment. Addressing these motions collectively herein, the court will enter judgment as a matter of law that defendants do not infringe the '553 patent and grant a partial new trial on the issue of infringement of the '681 Patent.

II. STANDARDS OF REVIEW

A. Renewed Motion for Judgment as a Matter of Law

[HN1] Pursuant to *Federal Rule of Civil Procedure 50,* a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial, if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Walter v. Holiday Inns, Inc., 985 F.2d 1232, 1238 (3d Cir. 1993)* (citation omitted). [HN2] If the court denies a motion for JMOL during trial, the motion may be renewed within ten days of entry of judgment in the case. *FED. R. CIV. P. 50(b).* [HN3] To prevail on a renewed motion for JMOL following a jury trial, a party "'must show that the jury's findings, presumed or express, are not [*6] supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)* (quoting *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)).* [HN4] "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp., 732 F.2d. at 893.* [HN5] In assessing the sufficiency of the evidence, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. *Id.; Richardson-Vicks Inc. v. UpJohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).* [HN6] The appropriate inquiry is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. *Dawn Equip. Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).* [HN7] The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of [*7] the evidence." *Perkin-Elmer Corp., 732 F.2d at 893.*

B. Motion for a New Trial

[HN8] The court may grant a new trial pursuant to *Federal Rule of Civil Procedure 59* "for any of the reasons for which new trials have heretofore been granted in actions of law in the courts of the United States." *FED. R. CIV. P. 59(a).* [HN9] A court should grant a new trial in a jury case, however, only if "the verdict was against the weight of the evidence . . . [and] a miscarriage of justice would result if the verdict were to stand." *Williamson v. Consolidated Rail Corp., 926 F.2d 1344, 1352 (3d Cir. 1991).* In making this determination, the trial judge should consider the overall setting of the trial, the character of the evidence, and the complexity or simplicity of the legal principles which the jury had to apply to the facts. *Lind v. Schenley Industries, Inc., 278 F.2d 79, 89 (3d Cir.), cert. denied, 364 U.S. 835, 5 L. Ed. 2d 60, 81 S. Ct. 58 (1960)*

III. DISCUSSION

A. Defendants' Renewed Motion for Judgment as a Matter of Law

1. The Jury's Verdict That the Patents-In-Suit Are Not Obvious, Anticipated or [*8] Indefinite Is Supported by Substantial Evidence.

a. Obviousness

The defendants contend that both the *'681* and '553 Patents are invalid as obvious under *35 U.S.C. § 103.* [HN10] Whether or not a patent is obvious over the prior art is a question of law. *See Richardson-Vicks v. Upjohn Co., 122 F.3d 1476, 1479 (Fed Cir. 1997); see also Kar-*

sten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1384-85 (Fed Cir. 2001). Section 103 provides:

> [HN11] A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S. § 103. Put simply, [HN12] an invention is invalid if "the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." [*9] *Graham v. John Deere Co., 383 U.S. 1, 15, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).* [HN13] Obviousness cannot be based on "the hindsight combination of components selectively culled from the prior art to fit the parameters of the invention." *ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed Cir. 1998).* [HN14] The Supreme Court has set forth four factors relevant to determining obviousness: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) other secondary considerations. *Graham, 383 U.S. at 17-18.* Evaluating the *Graham* factors in view of the evidence adduced at trial, it was not unreasonable for the jury to have concluded that the Patents-In-Suit were not obvious.

Indeed, PharmaStem proffered ample evidence to support the jury's verdict. [HN15] Both a suggestion to make the composition or carry out the claimed process and a reasonable expectation of success must be found in the prior art to support a conclusion that a patent is obvious. *See* [*10] *In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991).* At trial, PharmaStem presented testimony that there were problems associated with transplant tissues used prior to the Patents-In-Suit. Bernstein Tr. at 2035-2038. There was also tremendous skepticism in the transplant field regarding the use of cord blood as a transplant tissue, Bernstein Tr. at 2043-204, and the references ViaCell asserts (namely Koike, Knudtzon and Vidal) did not overcome this skepticism. Bernstein Tr. at 2045-2048, 2054-2060. Finally, testimony established that those in the field of transplantation were surprised at the result of the first cord blood transplant conducted by the inventors of the Patents-In-Suit. Bernstein Tr. at 2061-2062. *See also* Wagner Tr. at 1378-1379. It is true that ViaCell capably highlights record evidence as to the meaning one of ordinary skill would attach to the alleged prior art references. Base upon the record evidence, a jury could have found that the Patents-In-Suit were obvious. This jury did not, however, and the aforementioned evidence provided it with sufficient basis to reach the conclusion that, prior to the inventions of the Patents-In-Suit, those in the [*11] field of hematopoietic reconstitution would not have expected cord blood to be a successful transplant tissue.

The jury also received an abundance of evidence to support the secondary considerations of long felt need, commercial success, failure of others, copying, and unexpected results. *See e.g.,* Bernstein Tr. at 2036, 2060-2061; Wagner Tr. at 1187; Tr. Ex. 413. Additionally, with respect to the '681 patent, the jury was permitted to consider the fact that the Patent and Trademark Office ("PTO") considered the alleged prior art in the reexamination and ultimate reissue of that patent. Similarly, during examination of the '553 Patent, the PTO considered the Ende, Prindull, and Knudtzon references, a fact which the jury was also entitled to consider in evaluating their combined effect on the obviousness issue. The court is not to "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp., 732 F.2d at 893.* In view of this standard, there is no basis to overturn the jury's finding that the Patents-In-Suit are not obvious.

b. Anticipation

Likewise, the jury's finding that the Patents-In-Suit are not invalid [*12] for anticipation is supported by substantial evidence. The defendants first contend that the *'681* patent is anticipated by Koike because the latter discloses each limitation of the former's claims. [HN16] "An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention." The *'681 Patent* claims a cryopreserved therapeutic composition comprising "viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a single human collected at the birth of said human, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult." To anticipate the *'681 Patent* Koike must demonstrate that stem cells were present in umbilical cord blood. There is ample evidence in the record establishing that Koike did not demonstrate stem cells. For example, Dr. Wagner's cross examination testimony stated that Koike did not prove that there were stem cells in umbilical cord blood. n2 Wagner Tr. at 1333. Dr. Bernstein [*13] also testified that the reference does not teach stem cells nor a therapeutic composition for use in

hematopoietic reconstitution. Bernstein Tr. at 2053. In this regard, the jury's verdict that the *'681 patent* is not anticipated by Koike is supported by substantial evidence so as to preclude judgment as a matter of law on the issue of anticipation.

> N2 Dr. Wagner's cross testimony could be further construed to support the conclusion that Koike did not cryopreserve enough cord blood, or teach cryopreservation of enough cord blood, for hematopoietic reconstitution of a human, whether adult or child, which is another limitation of the *'681 Patent*'s claims. *See* Wagner Tr. at 1342-1343.

The court reaches the same conclusion with respect to the *'553 Patent*. The *'553 Patent* claims in pertinent part:

> A method for hematopoietic or immune reconstitution of a human comprising:
>
> (a) isolating human neonatal or fetal blood components containing hematopoietic stem cells;
>
> (b) cryopreserving the [*14] blood components; and
>
> (c) introducing the blood components into a suitable human host.

It is undisputed that Koike did not introduce cord blood into a human, which is a necessary limitation of the *'553 Patent*. The defendants claim that Koike's suggestion that introducing the stem cells into a human host should be done is a sufficiently enabling disclosure to warrant a finding of anticipation. Even so, the record contains substantial evidence from which a jury could find that a person of ordinary skill in the art would not have been so enabled. For example, Dr. Wagner testified that Koike did not do a transplant, Wagner Tr. at 1333, and Dr. Bernstein testified that Koike does not introduce stem cells into a human or teach hematopoietic reconstitution, Bernstein Tr. at 2053-2054. Again, the jury's finding that the Patents-In-Suit are not anticipated n3 is supported by substantial evidence and the court will not overturn it on this basis.

> n3 Given the absence of record evidence showing that Koike's compositions contained an amount of stem cells sufficient to effect hematopoietic reconstitution of a human adult, the defendants' inherent anticipation theory is an equally unpersuasive basis on which to enter judgment as a matter of law on this issue. Although recognition of an element in the prior art before the critical date is not necessary, inherent anticipation still requires that the element necessarily be present. *Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed. Cir. 2003).*

[*15]

c. Indefiniteness

The defendants also argue that the '681 Patent is invalid because it is indefinite. Claim 1 of that patent covers "stem cells" "in an amount sufficient to effect hematopoietic reconstitution of a human adult." According to the defendants, this language is indefinite as a matter of law because it is specifically drawn to an amount of stem cells, but the patent is completely silent as to a quantity. In this regard, they claim that it does not provide sufficient notice of the scope of the invention. The court is not persuaded.

Section 112 provides in pertinent part:

> [HN17] The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. [HN18] The statute requires the patentee to provide the public with clear notice of what activities infringe the patent. *See* [*16] *Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001)*; *Morton Int'l v. Cardinal Chem. Co., 5 F.3d 1464, 1470 (Fed. Cir. 1993)*. [HN19] "If the claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Shat-*

terproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624 (Fed. Cir. 1985) (citing Georgia Pacific Corp. v. United States Plywood Corp., 258 F.2d 124, 136 (2d Cir. 1958)). [HN20] Indefiniteness is a question of law for the court. *In re Jolly, 36 C.C.P.A. 825, 172 F.2d 566, 570, 1949 Dec. Comm'r Pat. 111 (C.C.P.A. 1949)*; *see also Union Pacific Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001)*. [HN21] "In a jury trial, if there are disputed factual issues related to indefiniteness, they may be submitted to the jury for resolution." [*17] *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 2004 U.S. Dist. LEXIS 10730, Nos. 99-274 (SLR), 99-876 (SLR), 2004 WL 1305849, *10(D. Del. 2004)* (citing *BJ Services Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1372 (Fed.Cir.2003))*. [HN22] Because a patent is presumed valid, the party asserting a defense of invalidity on the basis of claim indefiniteness bears the burden of proof by clear and convincing evidence. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.., 806 F.2d 1565, 1575-76 (Fed.Cir.1986)*.

It is true that the language of the '681 Patent does not specify an amount of progenitor cells nor a volume of cord blood, and the specification is silent as to a precise amount. However, these facts do not necessarily dictate that Claim 1 must fail for indefiniteness. Given that there is no determinate or determinable minimum amount of cord blood for therapeutic usefulness in humans, the record supports that the *'681 Patent*'s claim language is as precise as the subject matter permits. Moreover, the record contains evidence establishing that a person of skill in the art would have understood [*18] what an amount of cord blood stem cells sufficient to effect hematopoietic reconstitution of a human adult means. *See. Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 823 (Fed. Cir. 1988)*; *Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed. Cir. 1986)*. Dr. Moore, PharmaStem's expert on hematopoiesis, testified that the Patents-In-Suit provide the reader with ample information to determine the amount of cord blood needed for transplantation in adults or children, and that the scientific community has in fact performed numerous transplants into adults. Moore Tr. at 340-348; *see also* Harris Tr. at 635-636 (for defendants' witness skilled in art stating that an amount sufficient for usefulness in a clinical setting would be "a sample that contained enough of those cells for a successful transplant"). Thus, the court can find no basis to overturn the jury's verdict that the '681 Patent is not invalid for indefiniteness.

2. The Jury's Verdict That the Defendants Contributorily Infringe the [*19] **'553 Patent** Cannot Stand.

The defendants claim that PharmaStem did not prove that they contributorily infringed the '553 Patent in that PharmaStem failed to adduce evidence that any of them sold or offered to sell cryopreserved cord blood to a transplanter or that cryopreserved cord blood was used by a single entity or group of entities acting in concert or working together to infringe the patent. The court agrees. Relevantly, the claim language of the '553 Patent requires:

> A method for obtaining human neonatal or fetal hematopoietic stem or progenitor cells comprising:
>
> (a) isolating human neonatal or fetal blood components containing hematopoietic stem or progenitor cells;
>
> (b) cryopreserving the blood components; and
>
> (c) thawing the blood components, such that the stem or progenitor cells are viable.

Because none of the defendants thaw or inject cord blood, both required elements of the '553 Patent's claims, there can be no literal infringement of the '553 Patent.

PharmaStem would, however, still be entitled to a finding of infringement if the jury reasonably could have found that the defendants contributorily infringed the [*20] '553 patent. *See 35 U.S.C. § 271(c)*.

Section 271(c) states:

> [HN23] Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce

> suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271. The verdict form required the jury to answer three questions in the affirmative in order to find that any of the defendants contributorily infringed the '553 patent. Consistent with the appropriate legal standard, the jury was required to find that (I) "cryopreserved cord blood has no substantial noninfringing use," (ii) "defendants and transplant physicians are acting in concert or working together to complete the process of infringement of claims 13, 19, 47, or 57 of the [*21] '553 patent by performing each and every one of the steps in any of those claims," and (iii) "a Defendant has contributorily infringed the '553 patent by selling or offering to sell cryopreserved cord blood that was actually used by a third party in the direct infringement of any of claims 13, 19, 47, 53, or 57 of the '553 patent." Jury Verdict Form, Qtn. Nos. 3, 4, and 5.

PharmaStem correctly points out the existence of evidence to support the jury's affirmative answer to questions (I) and (ii) of the verdict form. The record supports a conclusion that cryopreserved cord blood is, predominantly, useful only for transplantation therapy, or the use covered by the '553 Patent. Indeed, PharmaStem adduced evidence by which a jury reasonably could have found that cord blood was viewed as medical waste prior to the inventions of the Patents-In-Suit. *See, e.g.*, Moore Tr. at 328; Broxmeyer Tr. at 365; Wagner Tr. 1195-1196.

Moreover, the jury also could have reasonably found that each of the defendants worked together with transplant physicians to complete the patented process of the asserted claims of the [*22] '553 Patent. At trial, PharmaStem adduced evidence that the defendants test the blood samples to ensure each one is sufficient for transplantation and thereby aid transplant physicians. Tr. Ex. 103; Tr. Ex. 96; Laleman Tr. at 659. The defendants marketing materials also indicate that they work with physicians in various capacities to effectuate the transplantation process. For example, CorCell's website states "CorCell and Community Blood Services (CBS) has formed a strategic partnership devoted to expertly testing, processing and storing quality cord blood stem cells for future transplantation." Tr. Ex. 516. ViaCell's founder, Cynthia Fisher, testified that the company's mission was "to provide a niche application area between the obstetrician, the Hem/Onc and the blood banking center, as far as enabling providing cord blood stem cell banking." Fisher Tr. at 707. Cryo-Cell advertises that the units of cord blood stem cells stored at its facility are transplant-ready. Tr. Ex. 98. In addition, PharmaStem presented evidence that each of the defendants has at least one representative who liaises in some capacity with transplant physicians, i.e., Dr. Goldberg of CorCell and Dr. O'Neil of [*23] Cryo-Cell. CBR designates a Director of the Facility to oversee procedures regarding the release of cord blood units for transplantation. Tr. Ex. 110. Viacell seeks advice and counsel on nucleated cell counts and volumes useful for transplantation from its Medical Scientific Advisory Board, on which five of the seven members are prominent transplant doctors or physicians with extensive experience in hematology, oncology, and/or transfusion medicine. Tr. Ex. 253, Tr. at 1461-63; *see also* Wagner Tr. at 1389. Finally, there is also evidence in the record showing that each of the defendants maintain records and/or other materials regarding its cord blood units which it releases to physicians to assist the transplantation process. CorCell maintains records on the cord blood units it releases, Tr. Ex. 274, and requests feedback from the transplant facility as part of its standard operating procedures, Tr. Ex. 215. Cryo-Cell provides directions to transplant physicians on how to thaw the cryopreserved cord blood unit it provides. Tr. Ex. 97. CBR has a similar document setting forth the detailed protocol between CBR and the transplant physician when a cord blood unit is requested and [*24] released. Tr. Ex. 110. In view of this evidence, it was not unreasonable for the jury to have found that the defendants and transplant physicians worked together to infringe the '553 patent.

Nevertheless, with respect to the third question on the verdict form, there is simply no evidence in the record to support the jury's affirmative answer. It is undisputed that the defendants do not own the cord blood units. Rather the units are owned by the clients, or families, and the defendants in turn provide services with respect to the processing and storing of the compositions. Although the defendants charge enrollment, processing, and banking fees with respect to their storage services, they do not *sell* or *offer to sell* the cord blood units. Indeed, the record evidence on this issue is clear that the defendants sell a service, not cord blood units. *See* Hendrix Tr. 1042; Tr. 2653; Wagner Tr. 1278.

Tellingly, PharmaStem cannot direct the court to a single fact in evidence that would support a finding that any of the defendants sell or offer to sell cord blood. PharmaStem attempts to overcome this deficiency in the record by arguing that *Section 271(c)* focuses on the financial [*25] benefit derived by the seller regardless of the source. But the statute could not be clearer. *Section 271(c)* [HN24] liability is clearly dependant upon the accused infringer's selling or offering to sell a component of the patented process, here cord blood units. *See 35 U.S.C. § 271(c)*. Drawing all reasonable inferences from the evidence in favor of PharmaStem, the court agrees with the defendants that the jury's finding on the element of contributory infringement is not supported by substan-

tial evidence. In this regard, the jury's verdict on contributory infringement cannot stand. The court finds as matter of law that the defendants' services do not infringe the *'553 patent*. n4

n4 Because the court finds that the defendants do not infringe the *'553 Patent*, it will not address the issue of willful infringement with respect to that patent.

B. Defendants' Motion for a New Trial

The defendants alternatively contend that the court should set aside the judgment and grant a new trial because [*26] the jury's verdict was against the great weight of the evidence. The court agrees with respect to the jury's finding that the 100 % of the defendants' cord blood units infringe the '681 patent and accordingly will grant a partial new trial on this issue.

1. Inventorship

The defendants first claim that a new trial is warranted because the great weight of the evidence established that the Patents-In-Suit are invalid for failure to name one of the inventors, Dr. Pablo Rubinstein. The court does not agree.

[HN25] Every patent receives the presumption that its inventors are the true and only inventors. *See e.g., Acromed Corp. v. Sofamor Danek Grp.,. Inc., 253 F.3d 1371, 1379 (Fed. Cir. 2001)*. Invalidity for failure to name an inventor must be established by clear and convincing evidence. *See id at 1379*. To be a joint inventor, one must "contribute in some significant manner to the conception of the invention." *Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997)*. Specifically, each person claiming to be an inventor must have contributed to the conception of the invention. [*27] *Acromed, 253 F.3d at 1379*. Beyond conception, the purported inventor must demonstrate that he made "a contribution to the claimed invention that is not insignificant in quality, when contribution is measured against the dimension of the full invention, and [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Id. at 1379*.

Although the defendants point to evidence from which a jury could have found Dr. Rubinstein's contributions to be significant, PharmaStem adduced at least an equal amount of evidence that his contribution did not rise to the level of inventorship. Indeed, a jury could conclude from the record that Dr. Rubinstein provided consultation on cryopreservation methods which were already available in the art. *See* Bernstein Tr. at 1176-1177. Moreover, Dr. Rubinstein admitted that he published his cryopreservation techniques more than one year prior to the inventions of the Patents-In-Suit, Rubinstein Tr. at 1176-1177, which would allow a jury to conclude that any contribution he made was rendered prior art by the time of the patenting of the invention. *See 35 U.S.C. § 102* [*28] ; *Hess v. Advanced Cardiovascular Sys., 106 F.3d 976, 981 (Fed. Cir. 1997)*. In light of these significant pieces of evidence supporting the jury's finding that Dr. Rubinstein was not improperly omitted as an inventor, the court finds no basis to grant a new trial on the issue of invalidity for failure to name an inventor.

2. Inequitable Conduct

The defendants also argue that the jury's finding that PharmaStem did not engage in inequitable conduct before the PTO in the procurement of the *'681* and '553 Patents is against the great weight of the evidence. The court, however, is not persuaded that the jury's finding on this issue warrants a new trial. [HN26] The burden is on the party seeking to invalidate the patents to prove inequitable conduct by clear and convincing evidence. In view of the defendants' burden, the jury's verdict was not against the great weight of the evidence.

As evidence of PharmaStem's alleged inequitable conduct, the defendants point to the PharmaStem's failure to disclose two pieces of information to the PTO. First, after PharmaStem had presented its arguments to the PTO in reexamination, but several months before the '681 Patent reissued, [*29] the European Patent Office ("EPO") denied PharmaStem's European counterpart application, rejecting its argument that Koike does not teach stem cells. PharmaStem did not bring the EPO's rejection of its argument to the attention of the PTO before reissue. Second, in its opinion, the EPO cites the 1997 Broxmeyer article for the proposition that relevant scientific community considered progenitor cell assays to be reliable assays for stem cells. In view of these facts, the defendants argue that the jury's finding that PharmaStem did not engage in inequitable conduct before the PTO is against the great weight of the evidence.

[HN27] "One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." *Molins, 48 F.3d at 1178*; *accord Rockwell Techs. LLC v. Spectra-Physics Lasers, Inc., 2002 U.S. Dist. LEXIS 5180, 2002 WL 531555, at *3 (D. Del. Mar. 26, 2002)* [*30] . "Materiality and intent to deceive are distinct factual inquiries, and each must be shown by clear and convincing evidence." *Life Techs., Inc. v. Clontech Lab., Inc., 224 F.3d 1320, 1324 (Fed. Cir. 2000)*; accord

*ISCO Int'l, Inc. v. Conductus, Inc., 279 F. Supp. 2d 489, 2003 WL 22006253, at *6 (D. Del. 2003)*: [HN28] Patent applicants have a duty to disclose to the PTO "any material prior art or other information cited or brought to their attention in any related foreign application." Manual of Patent Examining Procedure § 2001.06(a) (4th ed., rev. 8, Oct. 1981). However, [HN29] a finding of inequitable conduct for nondisclosure of information requires proof that the applicant made a deliberate decision to withhold a known material reference from the PTO. *See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995).*

Given the controlling standards, PharmaStem adduced significant evidence to rebut the defendants' inequitable conduct case. Specifically, the EPO's decision applied European, as opposed to United States, patent laws, and examined different claims than the ones at issue before the PTO in the reexamination. Tr. Ex. 1013. [*31] Moreover, there is no dispute that PharmaStem disclosed Koike to the PTO in the reexamination, and that the PTO came to its own conclusion as to what the reference taught. With respect to the Broxmeyer article, it was published nearly ten years after the initial filing of the Patents-In-Suit, and therefore not a prior art reference. Tr. Ex. 1015. Further lending credence to PharmaStem's view that the article was not material, the EPO characterized the Broxmeyer article as "indirect evidence" and cited it in the portion of the opinion on novelty, which was not at issue in the reexamination before the PTO. Tr. Ex. 1013. When viewed as a whole, the record more than supports a conclusion that PharmaStem did not possess the requisite intent to deceive the PTO and therefore did not engage in inequitable conduct.

3. Infringement of the '681 Patent

a. Dr. Hendrix's Testimony

As one of the bases for their motion for a new trial on infringement of the '681 Patent, the defendants contend that Dr. Mary Hendrix, PharmaStem's infringement expert, should not have been permitted to testify. During the pretrial stage of proceedings, the defendants objected to Dr. Hendrix's [*32] testimony in a motion *in limine* and then again at the close of trial moved to strike the doctor's testimony. The court denied both of these motions, but will revisit its rulings in light of the evidentiary record now before it.

[HN30] *Rule 702* has three requirements as to expert opinions: 1) the witness must be an expert; (2) the witness must testify to scientific, technical, or other specialized knowledge; and 3) the testimony must assist the trier of fact. *See United States v. Velasquez, 64 F.3d 844, 849, 33 V.I. 265 (3d Cir. 1995)* (citations omitted). The U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993)*, established a gatekeeping role for trial court judges in determining the admissibility of expert testimony on scientific evidence. When an expert bases opinion testimony on scientific knowledge, the testimony will not be admitted unless it is derived by the scientific method and is supported by "appropriate validation." [*33] *Daubert, at 590.* This standard of evidentiary reliability focuses on the scientific validity of the expert's methods rather than the soundness of his specific conclusions. *Id. at 589* ("[the] inquiry into the reliability of, scientific evidence . . .. requires a determination as to its scientific validity."); *see also Oddi v. Ford Motor Co., 234 F.3d 136, 145 (3d Cir. 2000); United States v. Shea, 957 F. Supp. 331 at 337.* An expert's opinion is reliable if it is based on the "methods and procedures of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his or her belief. *See Daubert, 509 U.S. at 589.*

The defendants contend that the subject of Dr. Hendrix's testimony was not one for which expertise was necessary in that she based her infringement opinion entirely on an analysis of the defendants' marketing materials, without ever considering any data regarding the composition of the defendants' cord blood units. Dr. Hendrix is an accomplished stem cell biologist, but is not qualified as an expert in marketing or advertising. [*34] Moreover, her so-called analysis of the defendants' marketing materials was well within the jury's common knowledge, common sense and common experience. *See United States v. Stevens, 935 F.2d 1380, 1399-1400 (3d Cir. 1991)* (upholding [HN31] *Federal Rule of Evidence 403* exclusion of expert testimony regarding eye witness identification where the evidence was susceptible of elucidation without specialized knowledge and jury could have ascertained through common sense). In view of these considerations, the court is persuaded that Dr. Hendrix's conclusion, evidenced in her expert report and adduced through her testimony, that 100 % of the defendants' cord blood units infringe the '681 Patent was based upon a legally improper methodology that was unreliable as a matter of law under *Daubert.*

Significantly, Dr. Hendrix's admitted that she did not review or analyze any of the defendants' cord blood samples in reaching her opinion. Hendrix Tr. at 1038. Moreover, she explicitly testified that her opinion that all of the defendants' cord blood units infringe the [*35] '681 Patent was based on the fact that the defendants "promise stem cells for pediatric and adult transplantation." Hendrix Tr. at 1021. In this regard, her opinions are not based upon any methods or procedures of science in general and certainly not upon her specific expertise as a stem cell biologist, no matter how knowledgeable she may have been in that field. The court therefore deter-

mines that her opinion of infringement is no more than a lay-person's interpretation of the defendants' marketing materials. The materials relied upon by Dr. Hendrix may be persuasive on the issue of infringement, but permitting PharmaStem to couch its presentation of this evidence in the form of an expert opinion was an error.

B. The Lack of Record Evidence that 100 % of the Defendants' Units Infringe the '681 Patent

Claim 1 of the '681 Patent covers compositions containing stem cells "in an amount sufficient to effect hematopoietic reconstitution of a human adult." To prove infringement, therefore, PharmaStem was required to adduce evidence that the defendants cord blood units contained an amount of stem cells sufficient for transplantation into an adult. In the absence of Dr. [*36] Hendrix's testimony, the record is void of any proof to support a finding that 100 % of the defendants' cord blood units infringe the *'681 Patent*. To the contrary, the record overwhelmingly indicates that cord blood units will *not all* contain sufficient cells to reconstitute an adult. *See* Wagner Tr. at 1270; *see also* Tr. Ex. 1370 at 30 (PharmaStem telling the PTO that cord blood units "are highly variable in their stem cell content such that any particular cord blood collection may have low or no stem cells"). The jury's finding that *all* of the defendants' cord blood units infringe the *'681 Patent*, consequently, was against the great weight of the evidence.

At the same time, however, the record suggests that at least some of the defendants' cord blood units infringe in that there is evidence of successful transplants of the defendants' compositions into human adults. *See, e.g.,* Tr. Ex 115 (circumstantial evidence in the form of statements on CBR's website that a "newborn's cord blood stem cells were transplanted to her mother to treat chronic myelogenous leukemia," and that other transplants have occurred for the newborn's mother father and cousin); Tr. Ex. 103 [*37] (draft of ViaCord's private placement memorandum acknowledging that adult transplants have occurred). As a result, the court will grant a new trial, excluding Dr. Hendrix's expert testimony, on the issue of infringement of the *'681 Patent* and the resultant damages therefrom. n5

n5 Again, in light of its granting a new trial on the infringement issue, the court will not rule on the issue of willful infringement with respect to the *'681 Patent*.

IV. CONCLUSION

For the aforementioned reasons, the court will enter judgment as a matter of law that the defendants do not infringe the *'553 Patent* and grant a new trial on the issue of infringement and damages with respect to the *'681 Patent*. In all other aspects, the motions filed by the parties are denied. An order to this effect will accompany this opinion.

ORDER

For the reasons set forth in the court's memorandum opinion issued contemporaneously herewith, IT IS HEREBY ORDERED that:

1. Joint Renewed Motion by ViaCell, Inc, Cyro-Cell, Inc, [*38] CorCell, Inc, CBR Systems, Inc. for Judgment as a Matter of Law or in the Alternative, for a New Trial (or for Remittitur) (D.I. 448) is GRANTED IN PART.

2. PharmaStem, Inc.'s Motion for Enhanced Damages, Attorneys' Fees, Pre-Judgment Interest and Post Judgment Interest (D.I. 446) is DENIED.

3. PharmaStem, Inc.'s Motion for a Permanent Injunction (D.I. 447) is DENIED.

4. PharmaStem's Motion to Strike the Affidavit of Chris Adams (D.I. 487) is DENIED as moot.

5. The clerk shall enter judgment in favor of the defendants and against the plaintiff on the claim of infringement of *U.S. Patent No. 5,192,553*.

6. A new trial shall be held on the issue of infringement and damages with respect to *U.S. Patent No. 5,004,681*.

Dated: September 15, 2004

Gregory M. Sleet

UNITED STATES DISTRICT JUDGE

LEXSEE 1992 US DIST LEXIS 19383

RADIOFONE, INC v. PRICELLULAR CORP., ET AL

CIVIL ACTION NO. 91-4306 SECTION "I" (2)

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF LOUISIANA

1992 U.S. Dist. LEXIS 19383

December 10, 1992, Decided
December 11, 1992, Filed; December 14, 1992, Entered

CASE SUMMARY:

PROCEDURAL POSTURE: Both plaintiff cellular phone company and defendant cellular phone companies filed separate motions in limine.

OVERVIEW: The court granted in part and denied in part the parties' motions in limine. The court granted plaintiff's motions in limine: 1) to exclude evidence of damages for loss of prospective economic advantage because the court had already previously ruled that Louisiana law did not allow recovery for such damages under a claim for tortious interference with economic opportunities, and 2) to exclude expert testimony or evidence prepared by experts on plaintiff's actions in mitigation of its damages because the issue of whether plaintiff acted with diligence in mitigating its damages was for the trier of fact without the need of expert testimony. The court granted defendant's motions in limine: 1) to exclude the expert testimony of an individual that certain letters constituted a binding contract because the court would fully instruct the jury on the law to be applied for such determination, and 2) to exclude evidence and testimony regarding unrelated litigation in which certain defendants to this action had been named because allegations of a third party in a pleading were hearsay.

OUTCOME: The court granted in part and denied in part the motions in limine presented by both parties.

CORE TERMS: limine to exclude, motion in limine, specific performance, customer, expert testimony, pertaining, purported, unrelated, limine, minutes, reasonableness, relevance, formation, financial condition, exclude evidence, cellular, vice, speculative, absorbing, excluding, default, obligor, evidence relating, expert report, absorption, pre-trial, pertain, bind, evidence presented, negotiations

LexisNexis(R) Headnotes

Torts > Damages > Damages Generally
Torts > Business & Employment Torts > Interference With Prospective Advantage
[HN1] Louisiana law does not allow recovery for damages under a claim for tortious interference with economic opportunities.

Torts > Damages > Damages Generally
[HN2] Louisiana's Unfair Trade Practices and Consumer Protection Law does not provide a means of recovering that which Louisiana law has declared unactionable.

Torts > Damages > Mitigated Damages
[HN3] Louisiana law requires that plaintiff must have acted with such care and diligence as a man of ordinary prudence would under the circumstances in mitigating its damages.

Civil Procedure > Jury Trials > Province of Court & Jury
[HN4] It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.

Evidence > Relevance > Prior Acts, Crimes & Wrongs
[HN5] Under Fed. R. Evid. 404(b), evidence is admissible only where: the extrinsic offense evidence is relevant to an issue other than the defendant's character. The evidence must possess probative value that is not substantially outweighed by its undue prejudice and must meet the other requirements of Fed. R. Evid. 403. The line of reasoning that deems an extrinsic offense relevant to the issue of intent is valid only if an offense was in fact committed and the defendant in fact committed it.

Evidence > Hearsay Rule & Exceptions

[HN6] Allegations of a third party contained in a pleading are clearly hearsay.

Contracts Law > Remedies > Specific Performance
[HN7] La. Civ. Code Ann. art. 1986 provides that damages may be called for in a situation where specific performance of a contractual obligation is also granted. The "damages for delay" referred to in Article 1986 are triggered at the time the obligor is "put in default," according to La. Civ. Code Ann. art. 1989. La. Civ. Code Ann. art. 1991 specifically provides that an obligor may be put in default simply by means of a written request of performance.

Contracts Law > Remedies
[HN8] Damages in the form of lost profits are clearly contemplated, in La. Civ. Code Ann. arts. 1994 and 1995, as a result of an obligor's failure to perform or delay in performance. Lost profits are precluded in Louisiana contract law only where the calculation of such damages is speculative. Where the profits lost can be established with reasonable certainty, however, they are properly considered as an element of damages in a breach of contract case.

Evidence > Hearsay Rule & Exceptions > Admissions by Party Opponent
[HN9] As an admission of a party-opponent, the statements are not only not hearsay, they are possessed with an inherent trustworthiness that affords them "generous treatment" in terms of admissibility.

JUDGES: [*1] Mentz, Jr.

OPINIONBY: HENRY A. MENTZ, JR.

OPINION:

Before the Court are the motions in limine filed by Radiofone and the PriCellular defendants.

RADIOFONE'S MOTIONS IN LIMINE

I. Motion in limine to exclude evidence of damages for loss of "prospective economic advantage"

Radiofone's motion in limine to preclude Pricellular from offering any evidence of damages from lost opportunities to enter into contracts with cellular telephone users is **GRANTED**

This Court has ruled, in an order dated June 1, 1992, that [HN1] Louisiana law does not allow recovery by Pricellular for such damages under a claim for tortious interference with economic opportunities. Pricellular cannot re-label the very same conduct as a violation of Louisiana's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") and render it actionable. This Court's June 1, 1992 ruling specifically dismissed Pricellular's "lost opportunities to enter into contracts" claim, however labelled. The Fifth Circuit has recognized that the [HN2] UTPCPL does not provide a means of recovering that which Louisiana law has declared unactionable. *Am. Waste & Pollution Control Co. v. Browning Ferris Inc., 949 F.2d 1384, 1392 (5th Cir. 1991).* [*2]

II & III. Motion in limine to declare specific performance a mandatory remedy and to exclude evidence relating to alleged changes in the value and condition of the Abilene and Louisiana systems

Radiofone will be given an opportunity to prove at trial that it is entitled to specific performance. Such relief is certainly available under La.Civ.C.Art 1986. In the event the jury concludes that a contract, whether "to sell" (La.Civ.C.Art. 2462) or "of sale" (La.Civ.C.Art.2439) was formed by the August 24, 1990 letters, specific performance is then a form of relief that Art. 1986 gives this Court discretion to grant to Radiofone, unless the evidence presented to the Court shows such an award to be impracticable. La.Civ.C.Art 1986; La.Civ.C.Art. 2462; *J. Weingarten, Inc. v. Northgate Mall, Inc., 404 So.2d 896 (La. 1981).*

Defendants argue that Radiofone will get more than they bargained for if the jury finds the existence of a contract and specific performance of the contract is granted. The Court is given discretion, however, to "grant specific performance plus damages for delay if the obligee so demands." La.Civ.C.Art. 1986. Thus, the La. Civil Code [*3] contemplates that the obligor is to pay damages resulting from its failure to perform the obligations set forth in the contract. An award of specific performance can include an increase in the purchase price of the Louisiana system to allow for the actual expenses incurred in new construction after August 24, 1990. This will be a matter for the Court to decide. See, *El Paso Natural Gas Co. v. Western Building Assoc., 675 F.2d 1135, 1142 (10 Cir. 1982).*

In this regard, the Court recognizes that testimony, either lay or expert, pertaining to the value of the systems after August 24, 1990 is of no relevance to the issues of contract formation to be decided by the jury in this case. While such evidence may relate to the impracticability of specific performance or to damages that may accompany a grant of specific performance, these are issues that, under Louisiana law, must be decided by the Court, depending on the jury's verdict regarding the existence of a contract.

Accordingly, the Court orders in limine that all evidence pertaining to the value of either the Abilene system or the Louisiana 8 system at any time following Au-